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APPLIED MEDICAL RESOURCES CORPORATION
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,974	HART ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-38,75-77,79-81 and 83-89* is/are pending in the application.

4a) Of the above claim(s) *10-14,16-19 and 27-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 20-26, 34-38, 75-77, 79-81, and 83-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 84 and 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Lafontaine (U.S. Patent No. 6,520,939)). Lafontaine disclose a surgical access device having an elongate tubular member (110) with a working channel and an axis extending between a proximal end (112) and a distal end (114) and having a seal system at the distal end of the tubular member. The seal system comprises a septum seal comprising a septum (140) having an orifice sized and configured to seal in conjunction with a specific range of usable instruments and a zero seal (130) coupled to the septum seal and being sized and configured to seal when no instrument is in place within the working channel of the tubular member as the zero seal is normally closed (Figures 5A and 5B and lines 6-64 of column 4). As disclosed in lines 46-49 of column 4, the septum seal has an orifice which is sized and configured to provide a fluid tight seal about the devices inserted through the orifice. The zero seal is coupled or joined to the septum seal due to their positions as shown in Figures 5A and 5B and as disclosed in lines 6-22 of column 4 where Lafontaine discloses that the septum seal and the zero seal can be at a common position in the shaft of the tubular member. The zero seal is also considered to be coupled to the septum seal because the two seals are linked

together as they form a seal system together or because they form a pair of seals in the seal system. As to claim 88, the septum seal and the zero seal are formed in a monolithic construction as the septum seal and the zero seal are formed to result in a singular device, i.e., the tubular member, the septum seal, and the zero seal are parts of one device.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 85-87 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Haberland et al (U.S. Patent Application Publication No. 2005/0165433). Lafontaine discloses the device substantially as claimed. Even though Lafontaine discloses the zero seal as being coupled to the septum seal as discussed above, Lafontaine is silent on the specifics of the zero seal being coupled to the septum seal by bonding or by fusing or the device having a bonding feature for attaching the septum seal to the zero seal. Haberland et al disclose a surgical access device having a seal system with a septum seal (50) and a zero seal (60) where the zero seal is coupled to the septum seal by bonding or fusing (paragraphs [0048] and [0049]). Haberland et al also disclose a bonding feature or structure (36) for attaching the zero seal to the septum seal. It would have been obvious to one having ordinary skill in the

art at the time the invention was made to couple the zero seal to the septum seal of Lafontaine by bonding and fusing as taught by Haberland et al as both Lafontaine and Haberland et al disclose a surgical access device having a seal system with a zero seal coupled to a septum seal and Haberland et al teach that it is well known to use bonding or fusing to couple the zero seal to the septum seal so that the seal system can be formed as one unit. As to claim 86, it would have been obvious to one having ordinary skill in the art at the time the invention was made to attach the zero seal of Lafontaine to the septum seal of Lafontaine with a bonding structure as taught by Haberland et al as both Lafontaine and Haberland et al disclose a surgical access device having a seal system with a zero seal coupled to a septum seal and Haberland et al teach that it is well known to use a bonding structure to attach the zero seal to the septum seal so that the seal system can be formed as one unit.

As to claim 89, even though Lafontaine discloses the device as having a septum seal comprising a septum (140) having an orifice sized and configured to seal in conjunction with a specific range of usable instruments, Lafontaine is silent on the specifics of the septum comprising an elastomeric sheet having a frusto-conical shape. The septum seal (50) of Haberland et al comprises a septum having an orifice sized and configured to seal in conjunction with a specific range of usable instruments and comprising an elastomeric sheet having a frusto-conical shape (paragraphs [0043,] [0046] and [0047] and Figures 2, 5, 6, 9A, 10, 11, and 13). As disclosed in paragraphs [0043] and [0046], the septum comprises a sheet which is elastomeric and the septum seal (50) as a whole is disclosed as having an elastic range to readily accommodate the

instruments. As seen in Figure 9A, the septum comprises an elastomeric sheet having a frusto-conical shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the septum of Lafontaine with the septum comprising an elastomeric sheet having a frusto-conical shape of Haberland et al as both Lafontaine and Haberland et al disclose a septum having an orifice which can be used to provide a seal with instruments which are passed through the orifice and, thus, the septum of Haberland et al would be a mere substitution of parts performing the same function.

5. Claims 1, 3-9, 20-24, 34, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine (U.S. Patent No. 6,520,939) in view of Haberland et al (U.S. Patent Application Publication No. 2005/0165433). Lafontaine discloses a surgical access device having an elongate tubular member (110) with a working channel and an axis extending between a proximal end (112) and a distal end (114), a septum seal (140) integrally formed at the distal end of the tubular member, and a zero seal (130) disposed at the distal end of the tubular member and distal to the septum seal. The septum seal is integrally formed at the distal end of the tubular member as the septum seal is an integral part of the tubular member (lines 16-22 of column 4) and the septum seal and the tubular member form or are part of an integral or one-piece device. As disclosed in lines 46-49 of column 4, the septum seal has an orifice configured to receive an instrument and to provide a fluid tight seal about the instruments inserted through the orifice. The orifice is in the form of a hole or a piercing. The zero seal is sized and configured to seal when no instrument is in place within the

working channel of the tubular member as the zero seal is normally closed (Figures 5A and 5B and lines 6-64 of column 4). The zero seal is coupled or joined to the septum seal due to their positions as shown in Figures 5A and 5B and as disclosed in lines 6-22 of column 4 where Lafontaine discloses that the septum seal and the zero seal can be at a common position in the shaft of the tubular member. The zero seal is also considered to be coupled to the septum seal because the two seals are linked together as they form a seal system together or because they form a pair of seals in the seal system. Even though Lafontaine discloses the device as having a septum seal (140) having an orifice configured to receive an instrument, Lafontaine is silent on the specifics of the septum seal comprising an elastomeric sheet having a frusto-conical shape where the orifice is through the elastomeric sheet. Haberland et al disclose a surgical access device having a septum seal (50) and a zero seal (60) where the zero seal is coupled to the septum seal (paragraphs [0048] and [0049]). The septum seal (50) of Haberland et al comprises an elastomeric sheet having a frusto-conical shape and an orifice (51) through the elastomeric sheet (paragraphs [0043,] [0046] and [0047] and Figures 2, 5, 6, 9A, 10, 11, and 13). The orifice (51) is in the form of a hole or a piercing. As disclosed in paragraphs [0043] and [0046], the septum seal comprises a sheet which is elastomeric and the septum seal (50) as a whole is disclosed as having an elastic range to readily accommodate the instruments. As seen in Figure 9A, the septum seal comprises an elastomeric sheet having a frusto-conical shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the septum seal of Lafontaine with the septum seal comprising an

elastomeric sheet having a frusto-conical shape of Haberland et al as both Lafontaine and Haberland et al disclose a septum seal having an orifice which can be used to provide a seal with instruments which are passed through the orifice and, thus, the septum seal of Haberland et al would be a mere substitution of parts performing the same function. As to claims 75 and 76, the orifice of both Lafontaine and Haberland et al comprises a hole or a piercing.

As to claims 3 and 4, the zero seal is a duckbill seal with an intersecting sealing portion (134A) or a double duckbill seal with two or more intersecting sealing portions (134B) (lines 30-37 of column 4). As to claims 5 and 6, the device has a retaining portion (122) in the form of a flange or a ring at the proximal end of the tubular member (Figure 3). As to claim 7, Lafontaine disclose the tubular member and the septum seal forming a single unit or device (lines 6-22 of column 4) and the limitation of the tubular member and the septum seal being molded together as a single unit is considered to be a product-by-process limitation. A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art. Furthermore, substituting the septum seal of Lafontaine with the septum seal of Haberland et al would still result in the surgical access device having a tubular member and a septum seal being formed as a single unit or device. As to claim 9, the tubular member, the septum seal, and the zero seal are integrally formed as a single unit because the seals are an integral part of the tubular member and because the tubular member and the seals form a single unit or device (lines 6-22 of column 4). The device also has a placement device (14, 40, 50) as shown in Figures 1, 5B, and

8B). As to claim 21, the placement device is an obturator. As to claim 22, the placement device includes an elongate shaft with a proximal end, a mid-portion, and a distal end. As to claims 23 and 24, the proximal end of the elongate shaft has a handle and the mid-portion of the elongate shaft has a reduced profile (see Figure 1). As to claim 34, the seal has opposing lip portions (132) separated by a slit portion. As to claims 35 and 36, see lines 31-46 of column 4. As to claims 37 and 38, the lip portions are capable of allowing a surgical item such as a surgical suture to extend through the slit portion without disrupting a seal formed by the closure of the opposing lip portions.

As to claim 8, even though Lafontaine discloses the zero seal being coupled to the septum seal, Lafontaine is silent on the specifics of the zero seal being bonded, fused or over-molded with the septum seal. Haberland et al disclose the zero seal (60) being coupled to the septum seal by being bonded, fused, or over-molded with the septum seal (paragraphs [0048] and [0049]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to couple the zero seal to the septum seal of Lafontaine by bonding, fusing, or over-molding as taught by Haberland et al as both Lafontaine and Haberland et al disclose a surgical access device having a seal system with a zero seal coupled to a septum seal and Haberland et al teach that it is well known to use bonding, fusing, or over-molding to couple the zero seal to the septum seal so that the zero seal and the septum seal can be formed as one unit.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine and Haberland et al as applied to claim 1 above, and further in view of Fischell et al (U.S. Patent No. 6,017,328). Lafontaine and Haberland et al disclose the

device substantially as claimed. Even though Lafontaine discloses the device as having an elongate tubular member, Lafontaine is silent of the specifics of the tubular member being formed of an elastomeric material. Fischell et al disclose a surgical access member having an elongate tubular member or cannula section (220) and a septum seal (205) where the tubular member is formed of an elastomeric material (lines 31-34 of column 11 and lines 55-59 of column 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the tubular member of Lafontaine from an elastomeric material as taught by Fischell et al as both Lafontaine and Fischell et al disclose a surgical access device having an elongate tubular member and a seal and Fischell et al teach that it is well known to use an elastomeric material to form the tubular member as this would provide a soft, flexible member to be inserted into a patient's body (lines 48-52 of column 11).

7. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Haberland et al as applied to claim 22 above, and further in view of Green et al (U.S. Patent 6,497,716). Lafontaine in view of Haberland et al disclose the device substantially as claimed. However, Lafontaine is silent on the specifics of the distal end of the placement device being shaped like an hourglass or comprising a tapered, cone-shaped member. Green et al disclose a placement device (22) which is used to place an access device (14) where the distal end of the placement device is shaped like an hourglass and has a tapered, cone-shaped member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the placement device of Lafontaine with the placement device of

Green et al as both Lafontaine and Green et al disclose surgical access devices and placement devices for placing the access devices and Green et al disclose that it is well known to use a placement device having a distal end shaped like an hourglass and a tapered, cone-shaped member to place the access device.

8. Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Haberland et al as applied to claim 34 above, and further in view of Willis et al (U.S. Patent No. 6,767,340). Lafontaine in view of Haberland et al disclose the device substantially as claimed. Lafontaine discloses the duckbill seal (130) as having opposing lip portions separated by a slit portion. Haberland also disclose a duckbill seal (60) having opposing lip portions separated by a slit portion (paragraph [0045]). However, Lafontaine and Haberland et al are both silent on the specifics of the opposing lip portions being coated with or attached to a soft or occlusive material providing back pressure forcing the lip portions to close even when the duckbill seal is slightly open. Willis et al disclose a surgical access device (10) having a duckbill seal (42) having an occlusive material (80) attached to the lip portions (70, 72) of the duckbill seal. Willis et al disclose that the occlusive material provides back pressure forcing the lip portions to close even when the duckbill seal is slightly open as the occlusive member (80) bias the lip portions together in the sealed position (lines 20-35 of column 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the lip portions of the duckbill seal of Lafontaine with an occlusive material as taught by Willis et al as both Lafontaine and Willis et al disclose a surgical device having a duckbill seal with opposing lip portions and Willis et al teach

that it is well known to provide the lip portions with an occlusive material to bias the lip portions together in the sealed position. As to claim 36, the occlusive material of Willis et al is silicone as Willis et al disclose that the duckbill seal or valve member (42) is made of silicone (lines 50-57 of column 4). As to claims 37 and 38, the lip portions of both Lafontaine and Willis et al are capable of allowing a surgical item such as a surgical suture to extend through the slit portion without disrupting a seal formed by the closure of the opposing lip portions.

9. Claims 77 and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine (U.S. Patent No. 6,520,939) in view of Willis et al (U.S. Patent No. 6,767,340). Lafontaine discloses a surgical access device having an elongate tubular member (110) with a working channel and an axis extending between a proximal end (112) and a distal end (114), a septum seal (140) integrally formed at the distal end of the tubular member, and a duckbill valve (130) positioned distal to the septum seal. As disclosed in lines 46-49 of column 4, the septum seal has an orifice configured to receive an instrument. The duckbill valve has a plurality of opposing lip portions (132) (lines 30-37 of column 4). As shown in Figure 6B, at least two crossing slits separate the opposing lip portions as the slits extend across or cross from the edge shown at 110 to the center shown at 134B and each slit separates two opposed lip portions. Lafontaine disclose the device substantially as claimed. However, Lafontaine is silent on the specifics of the septum seal comprising an elastomeric seal and the duckbill valve having an occlusive material attached to the opposing lip portions. Willis et al disclose a surgical access device (10) having a septum seal (68) and a duckbill valve

having opposing lip portions (70, 72) where an occlusive material (80) is attached to the lip portions (70, 72). The septum seal comprises an elastomeric sheet with an orifice (as shown in Figure 4) through the sheet. The sheet is elastomeric as Willis et al disclose that the valve member (42) is made of a silicone elastomer (lines 50-57 of column 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the septum seal of Lafontaine with the septum seal comprising an elastomeric sheet of Willis et al as both Lafontaine and Willis et al disclose a septum seal having an orifice which can be used to provide a seal with instruments which are passed through the orifice and, thus, the septum seal of Willis et al would be a mere substitution of parts performing the same function. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to provide the lip portions of the duckbill valve of Lafontaine with an occlusive material as taught by Willis et al as both Lafontaine and Willis et al disclose a surgical device having a duckbill seal with opposing lip portions and Willis et al teach that it is well known to provide the lip portions with an occlusive material to bias the lip portions together in the sealed position (lines 20-35 of column 4). As to claim 79, the occlusive material of Willis et al is silicone as Willis et al disclose that the valve member (42) is made of silicone (lines 50-57 of column 4).

As to claim 80, the duckbill valve of both Lafontaine and Willis et al form a complete seal with a selected item extending through the lip portions (see Figure 5B of Lafontaine and Figure 7 of Willis et al). As to claim 81, the device of Lafontaine has an enlarged retaining flange (122) at the proximal end of the tubular member (Figure 3).

10. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Willis et al as applied to claim 77 above, and further in view of Haberland et al. Lafontaine discloses the device substantially as claimed. Even though Lafontaine discloses that the septum seal and the duckbill valve can be located at a common position, Lafontaine is silent on the specifics of a bonding feature for attaching the septum seal to the duckbill valve. Haberland et al disclose a surgical access device having a seal system with a septum seal (50) and a duckbill valve (60) with a bonding feature (36) for attaching the septum seal to the duckbill valve (paragraphs [0048] and [0049]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to attach the septum seal of Lafontaine to the duckbill valve of Lafontaine with a bonding feature as taught by Haberland et al as both Lafontaine and Haberland et al disclose a surgical access device having a seal system with a duckbill coupled to a septum seal by being located at a common position and Haberland et al teach that it is well known to provide a bonding feature for attaching the septum seal to the duckbill so that the septum seal and the duckbill valve can be formed as one unit.

Response to Arguments

11. Applicant's arguments filed June 21, 2010 have been fully considered but they are not persuasive.

As to Applicant's arguments in lines 5-12 of page 20, Lafontaine does disclose a septum seal comprising a septum having an orifice as recited in claim 84. Applicant has disclosed in line 15-19 of page 1 of the specification that a typical septum seal is an

elastomeric sheet or form with a hole or piercing generally at the center. The septum seal of Lafontaine comprises a septum (140) having an orifice as the septum seal comprises a form with a hole or piercing generally at the center. Thus, the polymeric O-ring of Lafontaine is a septum having a hole or orifice. Also, the orifice of the septum or O-ring of Lafontaine is sized and configured to seal in conjunction with a specific range of usable instruments as disclosed in lines 46-64 of column 4. Therefore, the broadest reasonable interpretation of a septum seal comprising a septum would include the O-ring of the Lafontaine device.

As to Applicant's arguments in line 13 of page 20 to line 1 of page 21, the septum seal and the zero seal of Lafontaine are formed in a monolithic construction as the septum seal and the zero seal are formed in a one-piece construction to result in a singular device where the tubular member, the septum seal, and the zero seal are parts of one device. Furthermore, the limitation of the septum seal and the zero seal being formed in a monolithic construction is considered to be a product-by-process claim and the determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

Applicant's arguments in line 17 of page 21 to line 2 of page 22 are not persuasive. Lafontaine does disclose a septum seal comprising a septum as discussed above. The septum seal of Lafontaine is part of the seal system at the distal end of the tubular member. Applicant indicates that Haberland et al fails to disclose or

suggest a seal system at the distal end of an elongate tubular member having a septum seal. However, the reference of Lafontaine is used to disclose the seal system at the distal end of an elongate tubular member having a septum seal and the reference of Haberland et al is used to disclose features that the reference of Lafontaine does not disclose. Thus, the reference of Haberland et al is not being used to disclose a seal system at the distal end of an elongate tubular member having a septum seal.

As to Applicant's arguments in line 15 of page 22 to line 8 of page 23, the septum seal or O-ring of Lafontaine is integrally formed at the distal end of the tubular member as the septum seal is an integral part of the tubular member such that the septum seal and the tubular member form or are a part of an integral or one-piece device. Furthermore, the limitation of the septum seal being integrally formed at the distal end of the tubular member is considered to be a product-by-process claim and the determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

As to Applicant's arguments in line 9 of page 23 to line 1 of page 24, the septum seal of Haberland et al does have a frusto-conical shape as recited in claim 1 as Haberland et al disclose a septum seal (50) comprising an elastomeric sheet having a frusto-conical shape where the portion of the seal (50), which is angled with respect to portion (53) in Figure 9A, has a frusto-conical shape. Applicant's remarks in lines 18-20 of page 23 that the periphery valve section (57) does not form a septum seal with tools

inserted therethrough are unclear as the specifics of the periphery valve section (57) has not been used in the rejection.

As to Applicant's arguments in lines 2-7 of page 24, the limitations of the septum seal being integrally formed at the distal end of the tubular member do not apply to the Haberland et al reference as the reference of Lafontaine has been used to disclose the septum seal being integrally formed at the distal end of the tubular member.

Applicant's arguments in lines 10-18 of page 24 are not persuasive. In lines 31-54 of column 1, Lafontaine discloses a prior art device where either the gasket of Figure 2A or the gasket of Figure 2B is present and discusses the advantages and disadvantages of each gasket. Lafontaine discloses a device having both a septum seal and a zero seal which addresses the individual disadvantage of each gasket. The septum seal of Haberland et is structured differently from either of the "disk-shaped" gaskets that Lafontaine teaches away from using and, furthermore, the device of Haberland et al has both a septum seal and a zero seal and, thus, also addresses the individual disadvantage of each "disk-shaped" gasket. Therefore, one skilled in the art would not be dissuaded by Lafontaine from modifying the device to include the septum seal of Haberland et al as the septum seal of Haberland et al functions in a similar manner to the septum seal of Lafontaine because an instrument can be inserted through both septum seals and the septum seals will both provide a fluid tight seal about the inserted instrument.

As to Applicant's arguments in lines 5-10 of page 28, the septum seal (68) of Willis et al comprising an elastomeric sheet with an orifice is also shown in Figure 3

where the septum seal is shown at 68 and the orifice is the hole shown between the two sections labeled 68. Figure 6 also shows the septum seal at 68 and the duckbill valve at 76.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Bhisma Mehta/
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767